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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,103	04/14/2000	Richard C. Deth	NU-431AX	8235

207 7590 05/20/2003

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BOSTON, MA 02109

EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/550,103

Applicant(s)

DETH, RICHARD C.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Declaration of Dr. Deth under 37 CFR 1.132, filed 3 March 2003 (Paper 11), has been entered.

Claim 5 has been amended (Paper 8). Claims 1-4 were previously withdrawn by the examiner (2 October 2002, Paper 7). Claims 5-9 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections/Rejections

Maintained Objections and/or Rejections

35 U.S.C. § 112, first paragraph, Enablement.

Claims 5-9 are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling for a method of identifying therapeutic agents for neuropsychiatric diseases involving the D4 receptor and in which phospholipid methylation has been shown to be affected, does not reasonably provide enablement for agents or processes involving other neuropsychiatric diseases, in which a clear link from the D4 receptor to phospholipid methylation has not yet been established. The reasons for this rejection were set forth at pages 3-5 of the previous office

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action (Paper 9, 10 October 2002). Claims 5-9 are drawn to a method of identifying a therapeutic process or agent for treating schizophrenia *or a related neuropsychiatric* disorder by using a cell line comprising the dopamine D4 receptor, and measuring levels of phospholipid methylation in the cells before and after administration of the candidate agent.

The specification discloses that phospholipid methylation is compromised in schizophrenic patients and that dopamine D4 receptors mediate the effect of dopamine on phospholipid methylation. The Specification does not disclose a link between neuropsychiatric disorders other than schizophrenia and phospholipid methylation. Furthermore, there is no link established between other neuropsychiatric disorders and the D4 receptor.

Applicants submit (3 March 2003, Paper 11, p 5) that “those of ordinary skill in the art would have known from the published literature that neuropsychiatric disorders other than schizophrenia involved dopamine D4 receptor-mediated phospholipid methylation”. Despite Applicant’s arguments, there is no enabling discussion or working examples disclosed in the instant application that cells other than the lymphocyte cell line from schizophrenic patients would function in the manner claimed.

The Declaration of Dr. Deth, under 37 CFR 1.132, submitted 3 March 2003, argues that autism, attention-deficit hyperactivity disorder and Alzheimer’s disease involve dopamine D4 receptor-mediated phospholipid methylation, and that therefore the lymphocyte cell line from schizophrenic patients can be used to find agents for treating these disorders (p. 3-5). The declaration includes statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. Without a discussion of the state of the art involved in

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D4 receptor-mediated phospholipid methylation, the statements made are not relevant to the issue of the scope of enablement of the claimed subject matter and provide no objective evidence thereof. See MPEP § 716. More complete discussion of the data surrounding the issue of D4 receptor-mediated phospholipid methylation would be useful in associating the disclosed experiments with *other neuropsychiatric disorders*.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation required to determine how to use the disclosed methods to find agents that can be used to treat *other neuropsychiatric disorders*, the lack of direction or guidance in the specification regarding the same, the lack of working examples that measure D4 receptor-mediated phospholipid methylation in cells other than the lymphocytes from schizophrenic patients, the state of the art which acknowledges the complexity of neuropsychiatric disorders, and the breadth of the claims which embrace methods of finding agents to treat *other neuropsychiatric disorders* -undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

5/19/03


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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